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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,647	07/07/2001	Dale R. Lovercheck	ANAL-VIT	6584

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,647	LOVERCHECK, DALE R.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-30,33-35,37-46 and 48-94* is/are pending in the application.

4a) Of the above claim(s) *49,55,57,58,62,63,70,85 and 88-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87, and 91-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendments filed October 28, 2003 have been entered.

The addition of claims 48-94 in amendments filed October 28, 2003 is acknowledged.

The cancellation of claims 1-25, 31-32, 36, and 47 is acknowledged.

Claims 26-30, 33-35, 37-46, and 48-94 are pending.

Claims 49, 55, 57, 58, 62, 63, 70, 85, and 88-90 are withdrawn from further consideration as non-elected species.

Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87, and 91-94 will be examined to the extent they read on the elected species.

The outstanding rejections under 35 USC 112, first and second paragraph are withdrawn in view of the amendments filed October 28, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56, 75, 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "discomfort reliever is widely used and widely recognized as being safe" recited in the claims renders the claims indefinite as to the discomfort reliever encompassed thereby. It is not clear what discomfort reliever would be

considered as "widely used" and "widely recognized as being safe". Some discomfort relievers are safe for one person but not for the others. It really depends on the patient's conditions and the medications he or she are taking at the time. Because these reasons, one of ordinary skill in the art would not be able to ascertain the metes and bounds of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87, and 91-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over SS Pharmaceutical (Comline Biotechnology & Medical, 1 Dec. 1992, page 4), Tsunoda (JP 2000-229853, English abstract is also provided) and Yeh et al. (US Patent 5,032,384) in view of Krause (Krause's Food, Nutrition & Diet Therapy, 1992, page 277-279).

SS Pharmaceutical teaches a composition containing ibuprofen and a high content of vitamin C (See the abstract).

Tsunoda teaches a pain-alleviating tablet containing 300-500mg of ibuprofen and about 30-50mg of vitamin C (See the abstract).

Yeh et al. teaches a composition containing an antioxidant, such as ascorbic acid, and a NSAID, such as ibuprofen, such that the weight amount of the antioxidant

and the NSAID is about 0.01 to 10% of the composition (See particularly the abstract, also col. 2, lines 9 and 48-49; col. 4, line 7-10). Yeh et al. also teaches that the composition can be formulated into oral dosage forms (See particularly col. 3, line 67).

The references do not expressly teach the composition to be indicated as in unit dosage form. The references do not expressly teach the composition to be indicated is in an enclosure. The references do not expressly teach the composition to be indicated is in an unit form as pill, tablet, or capsule. The references do not expressly teach the composition to be indicated is package with an indicator indicating the amount of each ingredients and the indication. The references do not expressly teach the indication of the recommended daily value of nutritional supplement.

Krause teaches that it is mandatory for nutrition manufacturer to list the recommended daily value of vitamin C of the food product on the package label (see page 279, Mandatory Listings of Food Label Section).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to indicate the amount of ibuprofen and vitamin C, as a unit dosage form, in the composition claimed herein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to enclose the ibuprofen-vitamin C unit dose tablet into a container with indicator (label) indicating the amount of each ingredients, the recommended daily value of the nutritional supplement, and the indication.

One of ordinary skill in the art would have been motivated to indicate the amount of ibuprofen and vitamin C, as a unit dosage form, in the composition claimed herein

and enclose the same into a container with indicator (label) indicating the amount of each ingredients, the recommended daily value of the nutritional supplement, and the indication. Firstly, employing the herein claimed amount of ibuprofen and vitamin C is considered as optimization of result effect parameters, which is obvious as being within the skill of the artisan, absent evidence to the contrary. Secondly, putting the drug dosage form into a container is considered obvious within the purview of skilled artisan. Thirdly, inclusion of a package insert or label, which is considered as indicator in the instant case, showing the "the name of drug, dosage, dosage form, route of administration, indication and direction of use" of a pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. Finally, law also mandates listing the recommended daily value of a nutritional supplement on the package label. Therefore, the method of indication of the herein claimed products is considered obvious to one of ordinary skill in the art since indicating the herein claimed information, regardless of what the drug is, is mandated by law.

Response to Arguments

Applicant's arguments filed October 28, 2003 with regards to the failure of the cited prior art to provide motivation or suggestion to combine have been considered, but are not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so

found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the instant invention is essentially comprising three steps: 1) the enclosing a unit dose of a predetermined amount of discomfort reliever, in which ibuprofen is the elected specie, with a nutritional supplement agent, in which vitamin C is the elected specie in an enclosure; 2) indicating the amount or recommended daily amount for the nutritional supplement, i.e., labeling; and 3) indicating the amount or the purpose of using the discomfort reliever. The primary references clearly teach the combination of ibuprofen and vitamin C is known. Although the primary references do not expressly teach the herein claimed labeling or in the instant case, indicating steps, the secondary reference show that labeling or indicating the use or the amount of the active ingredients is mandated by law, and therefore, obvious to one of ordinary skill in the art.

Applicant's arguments filed October 28, 2003 with regards to the failure of each cited prior art individually to teach the elements of the instant invention have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, when taking the references as a whole, it renders the herein claimed obvious.

Applicant's arguments filed October 28, 2003 averring the examiner's conclusion of obviousness being based upon improper hindsight reasoning have been considered, but are not found persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, as discussed above, the cited prior arts as a whole render the herein claimed invention obvious.

Applicant's arguments filed October 28, 2003 averring the cited prior art's failure to teach the indication of the instant method have been considered, but are not found persuasive. As discussed above, the law mandates the inclusion of the indication. Therefore, enclosing a leaflet or indication would have been obvious to one ordinary skill in the art.

Applicant's arguments filed October 28, 2003 averring superior results being present in the instant invention have been considered, but are not found persuasive. Applicant's arguments are flawed for at least three reasons: 1) It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical

and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, there is no data provided in the instant case to demonstrate unexpected benefits. 2) the cited prior art clearly teaches composition containing the exact same ingredients. According to the law, one of ordinary skill in the art is mandated to put the herein claimed labeling information with the composition, and therefore, reasonably expected and required. Therefore, such "superior results" as the applicant claimed would be expected. 3) Applicant constructively argues that the patentability of the instant invention hinges on the "label", indication, or the printed materials. Attention is drawn to *In re Miller* 164 USPQ 46 (CCPA1969) and *In re Gulack* 217 USPQ 401 (CAFC) 1983. In *Miller*, the Court relies on the fact that there is a functional relationship between a measuring cup and the indicia (printed material) on the cup. A cup is not a measuring cup without the indicia since one cannot employ the cup (without indicia) to take accurate measurements. In other words, the content of the printed materials bear no patentable weight unless a functional relationship between the label and the actives is found. In the instant case, a patient can take a medication even without having the written instructions at hand. The ultimate function of the instant composition relies not on the written instructions, but on the active pharmaceutical ingredient, i.e., ibuprofen and vitamin C, contained therein. The Court in *In re Gulack* also states that "where the printed material is not functionally related to the substrate,

the printed matter will not distinguish the invention from the prior art in terms of patentability." Here, the set of instructions is not functionally related to the composition because the composition can function as an active and effective drug even in the absence of the set of instructions (i.e., package insert or indication). Therefore following the reasoning in *Miller* and *Gulack*, we can conclude that the "printed material", i.e., the indication or package insert, does not patentably distinguish the instant claims over the prior art.

Applicant's arguments filed October 28, 2003 averring the cited prior art teaching away have been considered, but are not found persuasive. Please note that teaching away has to be explicit. In page 20, line 7-9, applicant states "Disclosure of antioxidant and/or synergistic vitamins as part of a pharmaceutical essentially teaches away from the invention.". In the instant case, vitamin C, the synergistic vitamin in Yeh et al., is the elected nutrition supplement compound in the instant case. It is not clear to the examiner why the cited prior art are teaching away when the cited prior art teaches the elected nutrition supplement compound.

Applicant's arguments filed October 28, 2003 averring the cited prior art's failure to teach the antioxidant/synergistic vitamin as useful for supplementing nutrition have been considered, but are not fond persuasive. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. In other words,

vitamin C will still be functioned as nutrition supplement regardless of whether the prior art teaches so.

Applicant's arguments filed October 28, 2003 with regard to all limitations of a claim must be considered meaningful have been considered, but are not found persuasive. In *Perkin-Elmer Corp v. Westinghouse Elec. Corp.*, the court ruled that when applying doctrine of equivalents in infringement, claims limitations cannot be ignored as insignificant or immaterial. The limitations in *Perkin-Elmer Corp v. Westinghouse Elec. Corp.* the court ruled not to ignore is structural, functional, and operational to the invention therein. The instant case is distinguished from that in which the herein claimed limitations drawn to labeling and indication, which is printed materials. The functional relationship between the herein claimed indication, i.e., printed materials, and the herein claimed active nutrition supplementing/discomfort relieving composition is absent. Please see the discussion above.

Applicant's arguments filed October 28, 2003 with regards to topical treatments of Yeh et al. have been considered, but are not found persuasive. Yeh et al. clearly teaches the composition be formulated into tablets, pills, capsule, and other oral dosage forms (See Yeh et al., col. 2, lines 13-15). Furthermore, the instant claims do not recite an oral dosage form. They only recite "oral consumable material". Oral consumable materials are necessarily formulated into oral dosage forms. They can be formulated into different kinds of dosage forms.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
Patent Examiner
Art Unit 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

1/23/04